K012530

AUG 31 2001

510(k) Summary of Safety and Effectiveness

Submitter:	Company Name:	Neuro-Vision, Inc.
	Address:	111 South Bedford Street Suite 100 Burlington, Massachusetts 01803
	Phone:	(781) 221-4680
	Fax:	(781) 221-7468
	Registration :	Pending

Manufacturer Information:

Company Name:	NeuroVision, Inc.
Address:	111 South Bedford Street Suite 100 Burlington, Massachusetts 01803
Phone:	(781) 221-4680
Registration Number:	Pending

Official Correspondent:	Richard E. Lippman, O.D., F.A.A.O.
Address:	C.L. McIntosh, Inc. 12300 Twinbrook Parkway Suite 230 Rockville, Maryland 20852
Phone :	301-770-9590
Fax:	301-770-9584

DEVICE IDENTIFICATION:

Trade Name:	AA-1 System for the Treatment of Amblyopia
Common Name:	Amblyopia Treatment Device
Classification Name:	Haploscope; Eye patch

CLASSIFICATION
Name and Reference: 21 CFR 886.1340 haploscope

REGULATORY CLASS Class I

COMMON NAME: Amblyopia Treatment Device

ESTABLISHMENT REGISTRATION: Pending

INDICATION for USE:

The AA-1 System is indicated for the treatment of amblyopia using an interactive computerized program in patients 9 years or older suffering from amblyopia.

SUBSTANTIALLY EQUIVALENT TO:

The Neurovision AA-1 System is substantially equivalent to an ophthalmic Haploscope, a Class I Exempt medical device that is an AC powered device consisting of two movable viewing tubes, each containing a slide carrier, a low intensity light source for illumination of the slides, and a high

intensity light source for creating an afterimage. The intended use of the device includes amblyopia treatment and treatment of suppression.

The Neurovision device is equivalent to the haploscope (Preamendments Device 886.1340) with respect to the intended use- treatment of amblyopia. Additionally, the subject device is further equivalent to a haploscope in its principal of action, in that the low intensity light stimulus on the haploscope slides are used to bring light stimulus to the eyes when the target slides are moved with respect to each other.

The Neurovision AA-1 System is also substantially equivalent to the Humphrey Visual Field Analyzer (K852639) in that both devices collect diagnostic information through the use of software that interprets data information and reports diagnostic information useful to the user employing the device for further diagnosis and or treatment in the given indication for use.

Lastly, the Neurovision AA-1 System is substantially equivalent to an Eye Shield (K896171) Eye Garter Company, and Eye Shield (K841599) Storz Instrument Company, that is customarily used to cover the good eye during amblyopic treatment of the amblyopic eye during treatment sessions to improve visual acuity in the affected eye.

DEVICE DESCRIPTION:

The device is a computerized interactive device that provides the user with a series of linear images oriented in vertical and horizontal planes on a video imaging screen that is designed to identify and correct visual dysfunction from reduced visual acuity by re-training the eye to utilize its optimal visual response in gaining an increased awareness of visual acuity through a series of training sessions. The device analyzes the patient's visual acuity deficiencies and sets a program for the user to increase the demand on the visual system resulting in an improvement of visual acuity. The device pre-programs a series of visual stimuli tasks and takes the patient through a series of interactive functions in identifying various objects on the video screen, and helps to provide an environment that increases visual response.

CLINICAL INVESTIGATION

A prospective randomized and controlled clinical investigation was conducted to evaluate the potential for improvement and retention of visual acuity in persons of 9 years of age or older who suffer from amblyopia (lazy eye) from any source. The investigation consisted of a series of treatment sessions in an interactive environment using a pre-programmed analysis of visual debilitation from amblyopia and a computerized software program that had analyzed the visual defect and carried the subjects through a series of sequential treatments designed to improve visual resolution capability. The investigation consisted of visual stimuli projected onto a video monitor and patient responses being recorded by the click of a computer mouse responding to the various visual stimuli. The computerized program archived the responses and analyzed the responses in preparing the subjects for the subsequent treatment session. Completion of the treatments was established when the subjects no longer improved visual acuity, and were stable to the same visual acuity readings for three consecutive visits. After a three month rest period from treatments, the subjects were measured for their ability to retain the visual improvement that was gained during the first phase of the treatments.

The investigation of the device demonstrated that the subjects who completed the study with the long term follow-up three month visit improved visual acuity performance by an average of 2.5 lines of visual acuity from their baseline visual acuity best corrected vision. Greater than 70% of the subjects showed consistency in visual improvement. The control group treated by placebo treatment showed no improvement and was detected earlier in the study

LABELING

The Neurovision AA-1 System for the Treatment of Amblyopia is provided with a User Manual for the Practitioner, and two additional brochures, one for the professional and one for the patient. The information is available from the company:

Neurovision, Inc.
111 South Bedford Street
Suite 100
Burlington, Massachusetts 01803
(781) 221- 4680

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Neuro Vision, Inc.
c/o Richard E. Lippman, O.D., F.A.A.O.
C.L. McIntosh, Inc.
12300 Twinbrook Parkway Suite 230
Rockville, Maryland 20852

Re: K012530
Trade Name: AA-1 System
Classification Regulation Number: CFR 886.1340
Regulatory Class: Class I
Product Code: HJT
Dated: August 3, 2001
Received: August 6, 2001

Dear Dr. Lippman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications Statement

510(k) Number (if known) K012530

Device Name: Vision Treatment System for Amblyopia (AA-1 System)

Indications for Use:

The Vision Treatment System is indicated for the treatment of amblyopia using an interactive computerized program in patients 9 years or older suffering from amblyopia.

Additional Claims:

Attributes of the Device:

-Improved Vision
-Improved Stereoscopic Vision
-Improved Contrast Sensitivity

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Presription Use ✓ OR Over -The-Counter Use _____

(Oprtional Format 1-2-96)

Donna L. McCarthy
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K012530